

### **REMARKS**

This Reply is responsive to the Office Action dated January 7, 2005. Entry of the amendments and remarks submitted herein and reconsideration of the claimed subject matter pursuant to 37 CFR §1.112 is respectfully requested.

#### **I. Status of the Claims**

Claims 22, 23, 25, 26, 28, 29, 33-37, 39, 47 and 48 were pending and under examination at the time of the Office Action dated January 7, 2005. Claims 30-32, 38 and 40-46 have been withdrawn and claims 24, 27, 28, 47 and 48 have been canceled. New claim 49 has been added. Thus, claims 22, 23, 25, 26, 29, 33-37, 39 and 49 remain pending and under examination.

#### **II. Amendments to the Claims**

Claim 22 has been amended above to indicate that the claimed polypeptide is isolated, and that it mediates relaxation of depolarized-intestinal smooth muscle when expressed in a cell. Claim 39 has been amended to indicate that agonist or antagonist activity is identified by measuring relaxation of depolarized-intestinal smooth muscle. Support for these amendments may be found in the specification at page 1, line 3, page 7, lines 10-11, and at page 20, lines 1-12. New claim 49 has been added, which specifies that the polypeptide of claim 22 comprises a sequence selected from the group consisting of SEQ ID NO: 5 and SEQ ID NO: 6. Support for this claim may be found in Example 3, on page 32. No prohibited new matter has been added by way of these amendments.

### **III. Rejections Under 35 U.S.C. §112**

Claim 39 was rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Essentially, the phrase “appropriate signal transductions” has been rejected because the specification has allegedly not asserted what transduction signals are appropriate. Without agreeing with the rejection and solely in an effort to expedite allowance of the present application, Applicants have amended claim 39 to indicate that agonist or antagonist activity is identified by measuring relaxation of depolarized-intestinal smooth muscle. Withdrawal of the rejection of claim 39 under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 22, 25, 29, 33, 34, 36, 37 and 39 were rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for polynucleotides encoding a protein of SEQ ID No. 14 and the portion thereof capable of binding ICYP, allegedly fails to enable other polynucleotides. According to the Office Action, the substantially pure polypeptide would not be expected to mediate inhibition of eosinophil chemotaxis outside of the cell membrane. Further, even if the claim were amended to indicate that the polypeptide mediates inhibition of eosinophil chemotaxis in the cell membrane, there is allegedly no teaching of an assay that could identify members of a genus of variants that could perform such a function. The Action further asserts that claim 39 is not enabled across the full scope of possible transduction signals that could be measured. Applicants respectfully traverse the rejection.

At the outset, Applicants note that claim 39 has been amended to indicate that agonist or antagonist activity is identified by measuring relaxation of depolarized-

intestinal smooth muscle. Such an assay is fully enabled by the specification (see, for instance, Example 2 and page 20, lines 1-12). Accordingly, withdrawal of the rejection of claim 39 under 35 U.S.C. §112, first paragraph, is respectfully requested.

With regard to claim 22 and claims dependent thereon, the Action asserts that there is allegedly no known method for screening functional variants that mediate inhibition of eosinophil chemotaxis. Applicants respectfully disagree, since it was pointed out to the Examiner in the previous Reply filed July 24, 2003, that methods of measuring eosinophil chemotaxis were known in the art, as evidenced by Sugasawa and Morooka, 1992, *Recent Advances in Cellular and Molecular Biology* 3: 223-27. Nevertheless, in an effort to expedite prosecution of the present application, Applicants have amended claim 22 above to indicate that the claimed polypeptide mediates relaxation of depolarized-intestinal smooth muscle when expressed in a cell.

An assay for measuring relaxant responses of depolarized intestinal smooth muscle is clearly disclosed and enabled by the specification as filed, for instance at page 20, lines 1-12. Given the state of the art of molecular genetics at the time the application was filed, the skilled artisan could readily create directed or random mutations in the disclosed sequences using standard genetic techniques, and screen the resulting proteins for the functional attributes recited in the claims without undue experimentation. Accordingly, withdrawal of the rejection of claims 22, 25, 29, 33, 34, 36 and 37 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 22, 25, 29, 33, 34, 36, 37 and 39 were also rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification so as to reasonably convey that the inventors, at the time the application was

filed, had possession of the claimed invention. According to the Office Action, simply describing human proteins does not put one in possession of proteins from other species (see page 12 of Office Action). Although the Examiner has agreed that Applicants' arguments regarding Example 9 of the Written Description Guidelines previously submitted on October 6, 2004, were persuasive in part, the Examiner believes that an assay to measure the inhibition of eosinophil chemotaxis does not exist so as to adequately support a genus claim.

At the outset, Applicants respectfully note that, in contrast to what is asserted in the Office Action, the present specification describes more than just the human protein. It also describes isolation and characterization of the rat receptor in Example 1 of the specification. Furthermore, according to *University of California v. Eli Lilly & Co.* as discussed in the Office Action at page 9, a description of a genus may be achieved by recitation of a representative number of species or recitation of structural features common to the genus. In this regard, the proteins of the claimed genus have been further described as containing the sequences of SEQ ID NO: 5 or SEQ ID NO: 6 as described in Example 3 and the declaration of Tosinari Sugasawa filed July 24, 2003. This common structural attribute is now recited in new claim 49.

In any case, Applicants respectfully disagree with the Examiner's position that an assay to measure the inhibition of eosinophil chemotaxis does not exist. As noted above, methods of measuring eosinophil chemotaxis were known in the art, as evidenced by Sugasawa and Morooka, 1992, *Recent Advances in Cellular and Molecular Biology* 3: 223-27. Nevertheless, in an effort to expedite prosecution of the present application, Applicants have amended claim 22 above to indicate that the claimed polypeptide

mediates relaxation of depolarized-intestinal smooth muscle when expressed in a cell. Such an assay is clearly disclosed in the specification and may be properly recited as a functional attribute of the claimed proteins (see page 7, lines 10-11 and page 20, lines 1-12). This, in combination with the stringent hybridization conditions already recited in claim 22, renders the claim allowable according to the standards set by the Patent & Trademark Office. Again, according to the Office's analysis (see Example 9, pp. 36-7 of the Written Description Guidelines Training Materials):

[A] person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that Applicant was in possession of the claimed invention.

Thus, given that claim 22 is of a similar type as the claim at issue in Example 9 of the Training Materials, and given that the specification contains a description of how to demonstrate that a given variant has the recited function, Applicants respectfully submit that claim 22 as amended above is adequately described by the specification.

Reconsideration and withdrawal of the written description rejection under §112, first paragraph, are respectfully requested.

This reply is fully responsive to the Office Action dated January 7, 2005.

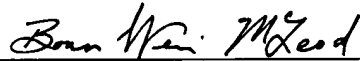
Therefore, a Notice of Allowance is next in order and is respectfully requested.

Except for issue fees payable under 37 CFR §1.18, the commissioner is hereby authorized by this paper to charge any additional fees during the pendency of this application including fees due under 37 CFR §1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 CFR §1.136(a)(3).

If the Examiner has any further questions relating to this Amendment or to the application in general, he is respectfully requested to contact the undersigned by telephone so that allowance of the present application may be expedited.

Respectfully submitted,

**Morgan, Lewis & Bockius LLP**



Bonnie Weiss McLeod  
Registration No. 43,255

Dated: June 7, 2005  
Morgan, Lewis & Bockius LLP  
Customer No. **09629**  
1111 Pennsylvania Ave., N.W.  
Washington, D.C. 20004  
202-739-3000  
202-739-3001